TESTIMONY OF DR. RICHARD RAYMOND
U.S. DEPARTMENT OF AGRICULTURE
UNDER SECRETARY FOR FOOD SAFETY
BEFORE THE
U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON AGRICULTURE
SUBCOMMITTEE ON LIVESTOCK, DAIRY, AND POULTRY

November 7, 2007

Good morning, Mr. Chairman, Congressman Hayes, and other Members of the Subcommittee. I am Dr. Richard Raymond, Under Secretary for Food Safety. I appreciate the opportunity to appear before you today to discuss the Food Safety and Inspection Service's (FSIS) ongoing efforts to protect public health.

I want to begin by addressing concerns expressed by Members of Congress regarding my comments about risk-based inspection (RBI) in processing and its relation to the recall by Topps Meat Company. I apologize for making any reference to RBI and Congress in the context of this recall. I have no basis upon which I could say RBI would have prevented this recall. There is certainly no correlation between the recall and congressional actions. I hope the Subcommittee will accept my apology.

I also want to notify the Subcommittee that based on the challenges posed to food safety by *E. coli* O157:H7 and what we have learned from recent recalls, I believe that we need to take additional time to strengthen our system and our data collection capabilities before moving forward with RBI in processing.

We welcome the Office of the Inspector General's report, expected by the end of the year, which is examining the data used in the development and design of risk-based inspection in processing. We will use that report to further focus our efforts.

In my testimony today, I want to start by briefly describing FSIS' food safety responsibilities. I will then focus on the rise in the number of recalls of FSIS-inspected products, especially related to *E. coli* O157:H7, and highlight some of the steps the Agency is taking to drive down the incidence of *E. coli* O157:H7. I will also explain FSIS' role during recalls, specifically during the Topps recall.

FSIS' Mission

As Under Secretary for Food Safety, I oversee FSIS. FSIS' mission is to ensure that meat, poultry, and processed egg products distributed in commerce for use as human food are safe, secure, wholesome, and accurately labeled. FSIS is charged with administering and enforcing the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Egg Products Inspection Act, portions of the Agricultural Marketing Act, and the regulations that implement these laws. FSIS also ensures compliance with the Humane Methods of Slaughter Act, which requires that all livestock be handled and slaughtered in a humane manner. The Agency is responsible for determining equivalence to Federal standards at the State level and among our foreign trading partners.

Our front-line personnel form the backbone of FSIS' public health infrastructure in establishments, laboratories and import houses throughout the country. In FY 2007, the

Agency had approximately 7,600 full-time in-plant and other front-line personnel protecting the public health in 6,000 federally-inspected establishments nationwide where FSIS inspection program personnel performed antemortem and postmortem inspection procedures to ensure public health requirements were met in the processing of over 44 billion pounds of livestock carcasses, almost 57 billion pounds of poultry carcasses, and about 3.5 billion pounds of liquid egg products. Approximately 60 cents of every food dollar in the United States is spent on foods that FSIS inspects.

In FY 2007, FSIS inspection program personnel conducted more than nine million procedures to verify that establishments met food safety and wholesomeness requirements. The amount of FSIS-regulated meat and poultry imports has remained approximately the same over the past five years, hovering around four billion pounds of meat and poultry from 29 of the 33 eligible countries. In addition, about six million pounds of egg products from Canada were presented for import re-inspection at U.S. ports and borders during the past year. FSIS also has Program Investigators nationwide who conduct food safety, food defense, and outbreak investigations and enforcements.

Recent Recalls

Since January 2007, there have been 19 recalls related to *E. coli* O157:H7 in beef this year. Nine of those have been associated with human illnesses. In 2006, there were eight *E. coli* O157:H7 related recalls, none of which were related to human illnesses. In 2005 there were only five *E. coli* O157:H7-related recalls. This year's experience has made

clear why we cannot be satisfied with the progress that we have made. We need to do more to strengthen our policies and programs.

As the increased number of recalls demonstrates, the challenges to public health are constantly evolving, and FSIS must evolve with them. Public health is a lot like riding a bicycle. If we're not moving forward, then we're falling down, and in public health there is no such thing as training wheels. We can't and won't let ourselves, our partners, or our nation's food safety system stagnate.

We are undertaking new, ongoing and upcoming actions to protect public health against the risk of *E. coli* O157:H7, including expanded testing and more rapid recalls. In June 2007, FSIS identified an increased number of *E. coli* O157:H7 positive tests in beef, as well as a larger number of recalls and illnesses caused by this pathogen than in recent years. As a result, FSIS increased the number of tests of ground beef for *E. coli* O157:H7 by more than 75 percent (from our base level of 1,100 to 1,943) in July. Even though the Agency saw nothing unusual in the positive sample rate in July, it has continued an increased sampling schedule for most raw ground beef establishments once per month (i.e., approximately 1,350 samples scheduled per month).

Earlier this year, FSIS began trim testing, the primary component in ground beef, in addition to ground beef itself. FSIS has also recently announced a new initiative to test additional components of ground beef. By testing earlier in the production chain, FSIS minimizes the likelihood that this contaminated source material could be used in ground

beef that is available to consumers. FSIS is also requiring countries whose beef is imported to the United States to conduct the same trim and beef component sampling or an equivalent measure, and the Agency will begin doing verification sampling of trim to supplement the Agency's ground product sampling at ports of entry. We will be analyzing imported and domestic product test results to determine whether we need to make further changes to FSIS policies and programs.

We have already made progress in getting recalls done more rapidly. As a result of the lessons learned from the Topps Meat company recall, FSIS now takes into account a broader, more complete range of evidence when evaluating whether to seek a recall or whether to take regulatory action. This gives the Agency a credible approach to more rapidly taking action when certain types of evidence are available. In two recent cases, FSIS acted upon epidemiological evidence that linked illness to opened, FSIS-inspected product found in consumers' freezers, where previously, we believed the Agency needed a test result from an intact or unopened package because of the possibility of cross-contamination. More than one million pounds of ground beef were recently recalled as a result of this change in our recall procedures.

We are examining our training and staffing patterns to ensure that inspection program personnel and supervisors are doing their jobs correctly, that they are held accountable, and that they have appropriate workloads and supervision.

We have implemented a number of key initiatives targeted to federally-inspected plants that produce raw beef products. FSIS determined that these steps were needed to ensure that inspection program personnel and the industry fully understand the nature of the challenge presented by *E. coli* O157:H7. The Agency is ensuring that suppliers, processors, and FSIS inspection personnel, will be able to identify an emerging problem as early as possible to prevent contaminated product from entering commerce.

Since September 28, 2007, FSIS inspection program personnel have been sending *E. coli* O157:H7 samples to FSIS labs for testing, irrespective of the company's test results. Previously, the Agency did not submit a sample to the lab if the company destroyed *E. coli* O157:H7-positive product or diverted it to cooking. While this practice of not submitting samples did not pose a human health risk, our new approach will allow us to increase the number of pulsed-field gel electrophoresis (PFGE), or DNA fingerprint patterns entered into PulseNet. PulseNet is the CDC's national molecular sub-typing network for food-borne disease surveillance and has searchable databases of all PFGE patterns from patients and food products in the United States.

On October 12, 2007, FSIS issued a notice instructing its District Offices to have Enforcement Investigation Analysis Officers schedule a food safety assessment upon notification of any Federal or State positive test result of *E. coli* O157:H7 in raw ground beef or ready-to-eat (RTE) meat and poultry products. The same action will be taken for positive sample results of *Listeria monocytogenes* or *Salmonella* in RTE products.

On October 12, 2007, FSIS also issued a notice instructing inspection program personnel to collect multiple follow-up samples of beef products in plants that have had a positive *E. coli* O157:H7 sample. Previously, FSIS collected only one follow-up sample following a positive test result. FSIS implemented this policy because analysis of *E. coli* O157:H7 sample data from 2000 through 2005 showed that plants are more likely to have a second positive sample if they have had a positive sample within the preceding 120 days. Suppliers of *E. coli* O157:H7-positive beef products will also be subject to this increased follow-up testing. Increased follow-up testing will provide the Agency with a statistically-based level of confidence regarding the likely presence of *E. coli* O157:H7 in FSIS-regulated product.

FSIS notified the beef industry that, as of November, all beef plants will be expected to verify that they are effectively controlling *E. coli* O157:H7 during slaughter and processing. The Agency also provided the industry specific examples of minimum controls that would meet the minimum criteria for a "well-controlled" process. Identifying which establishments achieve the minimum criteria, and which establishments do not, will provide FSIS the critical information on establishments with vulnerabilities.

FSIS inspection personnel began specialized training during the week of October 29, after which they will be equipped to complete a checklist describing the control measures and interventions used by raw beef suppliers and processors to control *E. coli* O157:H7. These checklists will be completed by November 30, and will be updated quarterly to

help the Agency more quickly identify potentially significant changes in production controls and ensure the plant takes corrective action. FSIS will analyze the checklist data and use it to adjust programs or policies as needed, such as where the Agency needs to conduct targeted verification testing and how to prioritize food safety assessments.

To supplement current hazard analysis surveillance activities, FSIS is developing and will implement in November, a process to assign specially trained investigators to evaluate corporate practices to control *E. coli* O157:H7. These investigators will identify the corporations whose controls are insufficient and may pose a threat to public health. This will help us identify the best practices at the establishments, generally, and within corporations. Once those best practices are identified, we can encourage better controls across-the-board, rather than on an establishment-by-establishment basis.

By January 2008, the Agency will begin using a newly developed test that will detect lower levels of *E. coli* O157:H7 contamination.

Also in January 2008, FSIS will begin routine targeted sampling for *E. coli* O157:H7 at slaughter and processing facilities. Currently, all plants have an equal chance of being tested. Under this new verification testing program, FSIS will test larger-volume operations and those with recent positive tests more frequently than in the past. Data from the checklists that will be generated by inspection personnel in November will also be used to determine testing frequency for establishments. The results of these checklists, in turn, could lead to new FSIS policies, directives, and regulations.

In fiscal year 2008, when FSIS conducts audits of countries exporting raw beef products to the United States, the Agency will place special emphasis on *E. coli* O157:H7 control measures.

It is critical that all of our food safety partners are informed and have the opportunity to share their ideas about the larger impact of FSIS' policies and regulatory actions on the food safety system. This way, we all work together to create the most effective food safety policies possible, in order to keep moving forward. Communication and trust is integral to that effort.

In September, FSIS participated in an *E. coli* O157:H7 workshop in Chicago, sponsored by the North American Meat Processors Association. This workshop focused on small-volume beef processors that specialize in producing ground beef and mechanically-tenderized steaks and roasts.

Beginning in October and continuing into November, FSIS will conduct outreach and training sessions around the country for small and very small processors of raw beef products, other stakeholders, and FSIS inspection program personnel. This training will focus on FSIS' new *E. coli* O157:H7 policies, as well as on lessons learned from the recent recalls associated with *E. coli* O157:H7. It will ensure that small and very small plants can effectively implement these measures to protect public health.

On October 17, FSIS, along with the Food and Drug Administration (FDA) and CDC, hosted a public meeting in Washington, DC, regarding pathogenic *E. coli* organisms other than *E. coli* O157:H7. We expect that as a result of this meeting, we will be able to ensure that any future steps we take to reduce the prevalence of pathogenic non-O157:H7 *E. coli* will be better understood by all of our food safety partners.

On October 18, Agency officials held a conference call with all 15 District Offices to fully explain the new policies to combat *E. coli* O157:H7 and to discuss implementation and how activities by inspection program personnel in plants will be monitored through Agency management controls.

Agency actions must be based on protecting public health. I want to emphasize how important this is to me, personally. As I have often said, I did not move to Washington to oversee recalls; I came to Washington to prevent food-borne illnesses. Even one illness is too many. With the actions we have announced and undertaken, I believe we are on the right track.

FSIS' Responsibilities Related to Recalls

As stated in FSIS Directive 8080.1, Revision 4, the purpose of a recall is to remove product from commerce as quickly as possible when FSIS has reason to believe it is adulterated or misbranded. FSIS may become aware of misbranded or adulterated product in commerce in several ways. For example, FSIS may be alerted to a potential recall situation by: 1) the company that manufactures or distributes the product; 2) test

results from FSIS sampling programs; 3) observations or information gathered by FSIS inspection program personnel in the course of their routine duties; 4) consumer complaints; or 5) epidemiological or laboratory data submitted by State or local health departments, other USDA agencies, or other Federal agencies, such as the U.S. Department of Heath and Human Services' (HHS) Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the Department of Defense.

FSIS' Recall Management Staff coordinates and convenes the recall committee, which makes recommendations for all recalls of FSIS-inspected meat and poultry products. When a company conducts a recall, which can and does occur 24 hours a day and seven days a week, FSIS notifies the public through a press release, which is posted on FSIS' Web site along with a photo of the product, when practicable. The Agency also issues recall information as quickly as possible through list-serves, e-mails, and faxes sent directly to stakeholders, including Members of Congress; news media; Federal, State, and local public health partners; and constituents. We have begun translating more of the recall releases into Spanish. Individuals can also subscribe to receive automatic e-mail notification of recall updates, including press releases, directly from FSIS' Web site.

The USDA Meat and Poultry Hotline (1-888-MPHotline or 1-888-674-6854) is staffed by food safety specialists who speak English and Spanish and can be reached from 10:00 a.m. to 4:00 p.m. Eastern Time, Monday through Friday. Recorded messages are available 24 hours a day on the Hotline, and during most recalls, FSIS records a message to inform the public of pertinent recall information.

AskKaren, FSIS' virtual representative, is available 24/7 to answer questions from the public about safe food preparation and handling. AskKaren includes information about recalls, including FSIS' role during recalls, how recalls are conducted, and how FSIS notifies the public during recalls. AskKaren also shows consumers where they can find information on specific recalls of FSIS-regulated products.

After the recall occurs, FSIS conducts effectiveness checks to ensure that consignees have received notice of the recall and are making reasonable efforts to retrieve and destroy the recalled product or return it to the recalling firm. Upon compliance, the recalling firm is officially notified by letter that the recall is completed, and no further action is expected.

In certain cases where FSIS has had good evidence that no adulterated product remains in commerce, meaning there is nothing to recall, but believes consumers may still have product in their homes, the Agency has issued public health alerts, which may contain all of the pertinent information found in a recall press release (i.e., company name and contact information, pounds of product implicated, epidemiological information, product labels, product production dates). In these cases, the Agency feels it is imperative to notify consumers of the potentially contaminated products that may still be in their homes -- for example, product that may be in their freezers.

To protect public health, FSIS has also issued public health alerts when the Agency has had evidence to implicate certain types of products in causing foodborne illness but is not able to definitively link the products to a specific establishment.

We also rely on our Federal, State and local public health partners in government, as well as consumer and industry representatives, to share this information with the public. Since public health alerts are very widely used in the public health community to warn consumers of potential health concerns (i.e., heat advisories, potential side effects of vaccinations, etc.), public health alerts are likely to get widespread local news media coverage, because it is framed as a public health issue instead of a business issue.

In order to improve voluntary recalls of meat and poultry products, FSIS published a proposed rule on March 7, 2006, which would allow FSIS to make available to the public lists of retail establishments that have likely received the products that are subject to the recall. The Agency held a public meeting on the proposed rule on April 24, 2006, and the public comment period ended on June 11, 2006. The Agency has reviewed the public comments and is currently revising the final rule.

FSIS issued this proposal because it concluded that making retail information available to the public will help consumers to better identify the recalled product. This valuable new information should help consumers to better protect themselves and their families.

Experience has shown that during a public health emergency, early, detailed, accurate and consistent information is one of our greatest tools to prevent panic, illnesses, and a collapse in consumer confidence. By working closely with our partners at all levels of government and industry, and among consumers, we can ensure that people have the information they need to keep themselves and their families safe.

Topps Meat Company Recall

The Topps recall of frozen ground beef products showed us that we needed to strengthen our policies and programs. I will outline the timeline of the actions that the Agency took, beginning with a report of a human illness, which is where we often start our active investigations.

This case was somewhat different because it began with an illness reported directly to USDA by a consumer, rather than a public health partner. On August 31, 2007, our Consumer Complaint Monitoring System received a report of a possible *E. coli* O157:H7-related illness concerning a consumer in Florida.

According to Agency protocols, that very same day, it was logged into our system and FSIS field investigators collected leftover product from that patient's freezer in Florida. Also that same day, this product was sent to our regulatory lab in Athens, Georgia, for testing.

On September 7, 2007, the Agency reported a positive *E. coli* O157:H7 test result from the product left over from that patient's freezer. At this point, we were not able to take recall action based on this initial test. Although we knew we were dealing with the O157:H7 strain, we wanted to conduct further testing to characterize this pathogen and determine definitively that it was linked to the Florida patient's illness.

The next line of testing was initiated, in the form of a pulsed-field gel electrophoresis or PFGE test. This is the so-called DNA fingerprint of a pathogen. It is a secondary test done to characterize the pathogen more completely. The test was initiated on September 7, and, as usual, this test took several days to complete.

Meanwhile, on September 8, 2007, regulatory lab in Athens, Georgia, had received an intact box of product from the Topps plant. Our protocol calls for 13 sub-samples to be tested. We treat each of them as an individual sample, and from this same product that had presumably caused the Florida patient's illness, we received 13 negative test results.

On September 14, 2007, we finally received the result of our PFGE fingerprint testing. By that time, the Florida Department of Health officials had uploaded their PFGE test results from the patient and CDC Pulse Net, and CDC's Pulse Net database managers confirmed that the PFGE patterns were indistinguishable. We then had information that linked the patient to the exposure, and in this case, again, it was leftover, opened product from the patient's freezer.

In accordance with our past protocol, the Agency did not immediately convene the recall committee. On September 20, 2007, FSIS learned of two additional illnesses in New York State. At that point, we were told that the illnesses were associated with Topps product, but the PFGE test results were not yet complete.

On September 22, 2007, we did get a report that the PFGE test results were complete in New York State, and that PFGE fingerprinting had linked these two illnesses with the products associated, but they differed from the *E. coli* O157:H7 fingerprint from the Florida case.

In other words, we had discovered three different PFGE patterns related to three different products from the same establishment, which caused three different illnesses.

Our investigators worked to solidify the link between the processing plant and attempted to explain the three different *E. coli* O157:H7 fingerprints. On September 24, 2007, New York State alerted FSIS to the fact that its State officials had already tested an unopened box of hamburger patties that they obtained in a supermarket, and that this box also tested positive for *E. coli* O157:H7. The next morning, September 25, FSIS reconvened its recall committee and that day, the Topps Meat Company issued its recall of 331,582 pounds of frozen ground beef products because of possible contamination with *E. coli* O157:H7. The product recalled was from three specific production dates in the plant and three separate PFGE patterns were linked to patients and ground beef products for those dates.

Also on September 24, 2007, FSIS began a food safety assessment, a thorough scientific review of the plant, in response to the illnesses associated with the consumption of Topps ground beef patties. The food safety assessment indicated that controls were insufficient to eliminate or reduce *E. coli* O157:H7 in the raw ground beef products.

On September 26, 2007, FSIS suspended inspection at the plant based on the September 25 recall; reported human illnesses; and the Agency's food safety assessment of the establishment, which found inadequate raw ground process controls and sanitation concerns. FSIS began reviewing Topps' suppliers, and on September 29, Topps expanded its original recall to include a total of approximately 21.7 million pounds of frozen ground beef products. The recall was expanded based on additional positive product testing reported by the New York Health Department, reported illnesses, and findings from the food safety assessment.

On October 4, 2007, FSIS took regulatory action (a Notice of Intended Enforcement) due to concerns about inadequate process controls for the plant's raw "not ground" operations. That same day, FSIS publicly outlined the timeline of the Topps recall, the preliminary findings from its investigation of the Topps recall, actions already taken by the Agency and further steps to reduce *E. coli* O157:H7.

On October 5, 2007, Topps announced it was going out of business.

As the result of the Topps Meat Company recall investigation, FSIS delisted Ranchers Beef, Ltd., on October 20, 2007. No product from that firm has been eligible to come into the United States since that date.

As announced on October 26, 2007, a joint investigation between the Canadian Food Inspection Agency (CFIA) and FSIS has identified a likely source of the multi-State outbreak of *E. coli* O157:H7 infections linked to the Topps Meat Company.

On October 25, 2007, the CFIA provided FSIS with PFGE patterns, or DNA fingerprints, from tests of beef trim from a Canadian firm, Ranchers Beef, Ltd. (Canadian establishment number 630). This firm provided trim to the Topps Meat Company. While the firm, which had been located in Balzac, Alberta, ceased operations on August 15, 2007, some product remained in storage and was collected and tested by CFIA as part of the joint investigation of the Topps recall and as part of CFIA's own investigation into 45 illnesses in Canada from *E. coli* O157:H7.

This piece of information, with the assistance from our food safety partners in Canada, helped us to determine a likely source of contaminated product which led to the September 29 Topps Meat Company expanded recall. We have a long history of cooperation and collaboration with CFIA.

On October 26, 2007, PulseNet provided verification to FSIS that this PFGE pattern indistinguishable from those of the patients who were ill and from positive tests

conducted by the New York Department of Health on product (both intact packages and open packages from patients' homes) that was later recalled by the Topps Meat Company on September 29. PulseNet is the CDC's searchable database of all PFGE patterns from patients and food products in the United States.

As of October 26, 2007, CDC reported 40 illnesses under investigation in eight states, with 21 known hospitalizations. The latest onset of illness is September 24, 2007. This summer was the first time this rare PFGE pattern had been seen in North America. Thirty-one of the 40 illnesses were indistinguishable from this rare PFGE pattern. Investigations continue in order to find the source of the other two PFGE patterns linked to Topps.

FSIS notified industry on October 26 to hold all boneless beef manufacturing trim from Ranchers Beef, Ltd., or raw products produced in whole or in part from these products until the joint investigation is completed. The Agency, on that same day, issued a notice to inspection program personnel in the field to retain these products.

As I announced on November 3, 2007, FSIS immediately began an audit of the Canadian food safety system that will focus on Ranchers Beef, Ltd. and will include other similar establishments that export beef to the U.S.

FSIS has instituted additional import requirements for meat and poultry products from Canada. Effective this week, FSIS will increase testing for *Salmonella*, *Listeria*

monocytogenes and *E. coli* O157:H7 and will require that shipments be held until testing is complete and products are confirmed negative for these pathogens. In addition, Canadian meat and poultry products will receive increased levels of re-inspection by FSIS to confirm they are eligible to enter commerce when presented at the U.S. border.

The audit and stepped up actions at the border are being conducted because of concerns about testing practices at Ranchers Beef, Ltd., that were discovered as part of the ongoing investigation. FSIS will review the preliminary findings of this audit to determine whether there is need to continue these additional interim requirements.

These measures are being taken to further ensure the equivalency of the system already in place. We continue to work together with our food safety partners both domestically and internationally to ensure imported meat and poultry products are produced under food regulatory systems equivalent to those in the United States, and provide the same level of protection against food hazards as is achieved domestically.

On November 2, 2007, FSIS Administrator Alfred Almanza and an additional senior FSIS food safety official met with their counterparts at the CFIA to inform them of increased testing and re-inspection requirements.

Conclusion

We will continue to engage the scientific community, consumers, public health experts, Congress, our own employees and all interested parties in an effort to identify science-

based solutions to public health issues to ensure positive public health outcomes. We all know that we can save lives with sensible science-based policies and together we'll do just that.

Mr. Chairman, thank you again for providing me with the opportunity to address the Subcommittee and submit testimony regarding the steps that FSIS is taking to remain a world leader in food safety and public health. I look forward to working with you to improve our food safety system.